Part VI: Summary of the risk management plan

Summary of risk management plan for hCG finished product 5000 IU, powder and solvent for solution for injection

This is a summary of the risk management plan (RMP) for hCG finished product 5000 IU, powder and solvent for solution for injection (hCG). The RMP details important risks of the product, how these risks can be monitor and minimized, and how more information will be obtained about hCG finished product 5000 IU, powder and solvent for solution for injection's risks.

hCG finished product 5000 IU, powder and solvent for solution for injection 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

hCG finished product 5000 IU, powder and solvent for solution for injection is authorized for anovulatory or oligoovulatory women as well as women undergoing superovulation prior to assisted reproductive techniques such as in vitro fertilisation (IVF - see SmPC for the full indication). It contains human chorionic gonadotrophin as the active substance and it is given by subcutaneous and intramuscular route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of hCG finished product 5000 IU, powder and solvent for solution for injection together with measures to minimise such risks and the proposed studies for learning more about the medicinal product, powder and solvent for solution for injection's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;•
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of hCG finished product 5000 IU, powder and solvent for solution for injection is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Summary of safety concerns	
Important identified risks	none
Important potential risks	none
Missing information	Use in women > 40 years

II.B Summary of important risks

Missing information	Use in females > 40 years of age
Evidence for linking the risk to the medicine	Age and other age-related factors may predispose to show a lower response to infertility treatments. Some studies and retrospective analysis have showed that IVF therapy may less effective but it is not known the potentiality in terms of safety.
Risk factors and risk groups	Females above 40s
Risk minimization measures	Only routine surveillance
Additional pharmacovigilance activities	None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of hCG finished product 5000 IU, powder and solvent for solution for injection.

II.C.2 Other studies in post-authorisation development plan

There are no other studies required for hCG finished product 5000 IU, powder and solvent for solution for injection.